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10/576,491

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

07/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

| | | | |
|------------------------------|--------------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 10/576,491 | Applicant(s) WU ET AL. | |
| | Examiner SHERIDAN SWOPE | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-64 is/are pending in the application.
- 4a) Of the above claim(s) 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-60 and 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' request for continued examination of March 17, 2010, in response to the action of September 18, 2009, is acknowledged. It is acknowledged that Claims 29-45 have been cancelled and Claims 46-64 have been added. Claims 46-64 are pending. The elected invention is directed to the protease polypeptide of SEQ ID NO: 2 and variants thereof. Claim 61 is withdrawn as being directed to non-elected subject matter. Claims 46-60 and 62-64 are encompassed by the elected invention and are hereby examined.

Priority

The priority date granted for Claims 46-60 and 62-64 is October 28, 2003; both US 60/515,000 and DK 2003 01562 disclose the recited subject matter of said claims.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claims 56 and 57, the phrase "residual activity of at least 50% after storage at 35°C when tested using the method disclosed in Example V" renders the claim indefinite because (i) the specification discloses two sections entitled "Example V" and (ii) the claim fails to designate how long the sample is stored at 35°C. The skilled artisan would not know the metes and bounds of the recited invention.

Any subsequent rejection based, on clarification of the above phrases and terms, will not be considered a new ground for rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 29-39, 42, and 43 under 35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994, for the reasons explained in the prior action, is withdrawn because said claims have been cancelled.

Claims 46-59 and 62-64 are herein rejected under 35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994 for the same reasons. In summary, Isono et al teach isolation of an alkaline proteases from *Fusarium solani* strains that, more likely than not, have activity in a detergent composition. More likely than not, Isono's *F. solani* alkaline proteases have thermostability, since an alkaline protease isolated from *Fusarium* sp has thermostability (Isono et al; Figs 3 & 4) and an aminotransferase isolated from *F. solani* has thermostability (Esaki et al; Abstract). Since the protease of SEQ ID NO: 2 is from *F. solani*, the skilled artisan would believe that, more likely than not, one or more of Isono's proteases isolated from *F. solani* strains is the same as the protease of SEQ ID NO: 2 herein. Isono et al further teach determining the pI and molecular weight of their proteases (col 5; 4&7), methods that result in ~100% purification. Therefore, Claims 46-59 and 62-64 are herein rejected under

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35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994.

In support of their request that the prior rejection be withdrawn, Applicants provide the following arguments, which are relevant to the current rejection. The reasons said arguments are not persuasive are found in each reply.

(A) The amino acid sequence of the *Fusarium* sp. S-19-5 alkaline protease is not disclosed in Isono et al.; however, as set forth in Applicants' prior response, many years after the filing of the Isono et al. patent application, Takeda disclosed the amino acid sequence of the *Fusarium* sp. S-19-5 (IFO 8884) alkaline protease in U.S. Patent No. 5,543,322 and Morita et al., 1994, *Biosci. Biotech. Biochem.* 58(4): 621-626. The characteristics of the alkaline protease described in the '322 patent and Morita et al. are consistent with the characteristics of the alkaline protease described in Isono et al. Thus, persons of ordinary skill in the art would expect that the alkaline protease described in the '322 patent and Morita et al. is the same protease described in Isono et al. at Examples 1-3.

(A) Reply: As acknowledged by Applicants, this is the same argument provided in prior responses. Applicants are referred to the reasons previously stated as to why this argument is not found to be persuasive. See, the action of September 18, 2009, pg 5, reply (A).

(B) The proteases described in Isono et al. are alkaline proteases, which belong to a different class of protease than trypsin-like proteases such as the protease of SEQ ID NO: 2 of the present invention.

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(B) Reply: As acknowledged by Applicants, this is the same argument provided in prior responses. Applicants are referred to the reasons previously stated as to why this argument is not found to be persuasive. See the action of September 18, 2009, pg 5, reply (B).

(C) Regarding the *Fusarium solani* (IFO 5232) strain, Isono et al. simply states that "[i]n the same manner as in Example 1," *F. solani* (IFO 5232) is cultivated, the culture is centrifuged to give supernatant fluid which is used as an enzyme solution, and enzyme activity with and without detergent is demonstrated from this alkaline protease-producing microorganism. See Isono et al., Example 6 and Table 5. In particular, Table 5 presents data that protease activity is measurable in an *F. solani* fermentation broth in the presence of the detergent LAS. However, Isono et al. do not purify or characterize the *F. solani* activity in any way.

(C) Reply: Isono et al teach how to use standard methods to isolate alkaline proteases from several strains, including *Fusarium solani* (IFO 5232) strain (col 1-3).

(D) A person skilled in the art would not expect *F. solani* to necessarily produce all of its proteases at any one time. Gene expression in microbes is carefully regulated to fit the environment conditions and developmental stage of the culture. Various literature references demonstrate this differential regulation of proteases in fungi. For example, Bye et al., Arch. Microbiol. 189:81-92 (2008) shows that the production of different subtilisins in the same fungus varies with growth substrate (Intro, Fig 1, and pg 91). Also see Paterson et al., Microbiology, 140:185-189 (1994). The culturing conditions of *F. solani* (IFO 5232) in Example 6 of Isono et al. are in fact quite different from Applicants' culturing conditions in the instant specification. Isono et al.

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(D) Reply: As acknowledged by Applicants, the skilled artisan would have known that protease expression is differentially regulated. Nonetheless, it would be expected that the alkaline protease of SEQ ID NO: 2 herein would be produced under more than a single, stringent culture condition. In addition, Isono et al teach a variety of culture mediums, times, and conditions to be used (col 2, lines 51-75 , col 5, top). It falls to Applicant to demonstrate that the protease of SEQ ID NO: 2 would not be produced under any of the conditions taught by Isono et al.

(E) Given that the culture conditions of *F. solani* (IFO 5232) in Isono et al. Example 6 are "[i]n the same manner" as those of Example 1, one of skill in the art could infer that the culture supernatant of *F. solani* likely includes the homolog of the alkaline protease isolated and characterized from *Fusarium* sp. S-19-5 (IFO 8884). Although Isono et al. provide no information as to which of the many proteases that *F. solani* could potentially produce is responsible for the effect seen in Table 5, one of skill in the art could reasonably infer that it is the homolog of the alkaline protease isolated and characterized from *Fusarium* sp. S-19-5 that actually provides this effect. This is further supported by the identification in Takeda's later '322 patent of *F. solani* as potential source for homologs to the cloned alkaline protease of IFO 8884. See '322 patent, col. 3, lines 4-9. As stated above, the protease produced from *Fusarium* sp. S-19-5 (IFO 8884) is not the same as the protease of SEQ ID NO: 2.

(E) Reply: See the replies above, (A)-(D).

For these reasons and those stated in the prior actions, Claims 46-59 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claim 44 under 35 U.S.C. 103(a) as being unpatentable over Isono et al, 1972 in view of Okuda et al, 2004 (FD 12-MAR-2003), for the reasons explained in the prior action, is withdrawn because said claim has been cancelled.

Claim 60 is herein rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al, 1972 in view of Okuda et al, 2004 (FD 12-MAR-2003), for the same reasons. The following is a reiteration of said rejection. The teachings of Isono et al and Hastrup et al are described above. Neither Isono et al nor Hastrup et al teach a detergent composition comprising their alkaline protease and, optionally, further comprising a cellulase, lipase, cutinase, oxidoreductase, another protease, an amylase, or a mixture thereof. Okuda et al teach a detergent composition comprising an alkaline protease and, optionally, further comprising a protease other than the alkaline protease of their invention, an hydrolase, reductase, oxidase, cellulase, cutinase, amylase, lipase, or a mixture thereof [0065]. It would have been obvious to a person of ordinary skill in the art to combine the teachings of Isono et al or Hastrup et al with the teachings of Okuda et al to produce a detergent composition comprising an alkaline protease of Isono et al or Hastrup et al and, optionally, further comprising a cellulase, lipase, cutinase, oxidoreductase, another protease, an amylase, or a mixture thereof. Motivation to do so derives from the simple substitution of the alkaline protease of Okuda et al with the alkaline protease of Isono et al or Hastrup et al (KSR

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International v. Teleflex Inc). The expectation of success is high, as detergent compositions comprising an alkaline protease and, optionally, further comprising a cellulase, lipase, cutinase, oxidoreductase, another protease, an amylase, or a mixture thereof were known in the art and used for cleaning methods. Therefore, Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al, 1972 or Hastrup et al, 1997 in view of Okuda et al, 2004 (FD 12-MAR-2003).

In support of their request that the prior rejection be withdrawn, Applicants provide the following argument, which is relevant to the current rejection. As explained in detail above, Isono et al. does not teach or suggest the claimed proteases. Okuda et al. disclose a detergent composition comprising an alkaline protease and one or more other enzymes. However, Okuda et al. does not teach or suggest detergent compositions comprising the proteases of the present invention. This argument is not found to be persuasive for the reasons stated above, (A)-(E).

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants'

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remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN SWOPE whose telephone number is 571-272-0943. The examiner can normally be reached on 11a-7:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652